

EDITOR'S PAGE

Is Participation in Clinical Research a Duty?

All of us are excited to hear the results of the latest clinical trials that may change practice and improve outcomes. Are we equally enthusiastic when it comes to acquiring this useful information? Experimental science is hard work but does not require volunteers to become subjects or investigators to invite people to become subjects. Clinical research, in contrast, brings into play the unavoidable interaction between individual autonomy and the common good. John Locke, in the 17th century, and Immanuel Kant, in the 18th century, spoke to the rights of the individual and their primacy. In the same period, Thomas Hobbes, and later Jean-Jacques Rousseau, developed the concept of the social contract, whereby participation of the individual benefits the community. Viewed in the context of clinical research, are the inalienable rights of the individual in conflict with the common good of the community? The current prevailing view is that participation in clinical research is beyond the call of duty, and individuals who agree to participate are unusual and therefore few. Opting in is the norm. Should opting out be considered? Has the pendulum between individual rights and community benefits swung too far in the direction of individual liberties? There is no argument that all clinical research must include consent that fully informs subjects of what is being proposed and that any participation is voluntary. However, are we impeding the advancement of clinical knowledge and the benefit to the community by not making participation in clinical research normal rather than unusual? Some disciplines and institutions practice this approach much more than others. Oncology is the prime example, in which clinical trials are often the norm, but it is less the case in cardiovascular medicine.

Is there really a conflict between the individual and the community? I think not, because knowledge of benefit, or lack thereof, although certainly of value to the community, also benefits the individuals who make up that community, including sometimes the subjects themselves who volunteer for trials, or their families. Although duty does not mean legal obligation, writing on this subject, a group from the Department of Bioethics at the National Institutes of Health concluded, "There needs to be a cultural shift in the more formal framework that is brought to participation in research...from participation in biomedical research being above the call of duty to being a moral obligation for everyone to do his/her part" (1).

If patients have a duty to participate in research, what about the physicians caring for those patients? The first obligation is clearly to the individual patient, but if the results of clinical trials are so interesting and potentially important to the rest of our patients, what is our duty to encourage participation of the appropriate patients in research? Of course, there are many other barriers to clinical research. One we discussed in a prior Editor's Page is the uneven reimbursement approval from the Centers for Medicare and Medicaid Services for medical device research that has been provisionally cleared by the U.S. Food and Drug Administration (2). Another impediment are the unreasonable time and work commitments of physicians in informing patients and discussing options. Clinical trials that impose significant economic hardships on physicians will have a hard time recruiting. It is concerning that many clinical trials are successfully enrolling patients only from countries with inadequate compensation for physicians' clinical work. Economics aside (and it is hard to put them aside), physicians have no less duty than patients to contribute to the medical knowledge to be gained from important clinical trials.

A word about the quality of trials for which patients request to volunteer: Not every trial is worthy of patients' and physicians' duty to participate. Some trials have little game-changing potential and are designed to support minor changes in the approval of devices, procedures, or therapies. Trial methods will not be understood by most subjects, but physicians participating in a trial should understand whether the methods are sufficient to answer the questions posed. Some trials will not rise to the level of convincing patients or physicians that it is their moral duty to



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contribute to the answer. Applying time and energy to answer the important questions will always be more effective and satisfying.

As we crowd into the main arena of the American College of Cardiology Scientific Sessions, the American Heart Association Scientific Sessions, the Transcatheter Cardiovascular Therapeutics Annual Meeting, or the European Society of Cardiology or EuroPCR meeting to hear the late-breaking trial results, or as we digest the published reports, we should be thankful to those patients and physicians who have made the findings possible. But we should also be concerned that we have not done enough to ensure timely completion of other clinical trials that will influence effective and efficient care. As “inconvenient” as it may sometimes be, helping our patients

discharge their duty to participate in the trials that will lead to benefit for all is our duty as well.

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